REMARKS

Reexamination and reconsideration are respectfully requested in view of the following remarks. The amendments are made solely to expedite prosecution, and Applicant does not thereby concede or imply that any aspect of the grounds for any rejection are proper. The amendments thus are without disclaimer and without prejudice to Applicant's rights to pursue any canceled subject matter in this application or in a continuing application.

1. Status of the Claims

Claims 1-6 and 8-35 stand pending. Claims 20-31 and 33-35 stand withdrawn. Claims 1-6, 8-19, and 32 stand rejected.

2. Support for the Amendments

The present claims are directed in part to a method comprising administering a composition in an amount sufficient to prevent decline of, improve, or enhance cognitive ability responses of a healthy adult person, where the amount represents a daily arachidonic acid intake of at least 200 mg. Support for administration of "at least 200 mg" is found in the specification at least at page 19, lines 13-14; page 26, lines 23-27; and page 20, line 24. Support for administration to a "healthy adult person" is found at page 19, line 17, and page 20, lines 14-26, for example.

The amendments accordingly do not introduce subject matter not supported by the specification as filed. The amendments are made without disclaimer or prejudice to Applicants' rights to pursue the subject matter in this or a continuing application.

3. Notice of Prosecution in Related Applications

The Office alleges that the present application is related to Applications No. 10/485,456 and No. 10/541,073.

In the '456 application, Examiner Pagonakis issued:

- a restriction requirement on October 12, 2007;
- a second restriction requirement on June 24, 2008;
- a non-final Office Action on December 9, 2008; and

- a final Office Action on July 16, 2009.

In the '073 application, Examiner Purdy issued:

- a restriction requirement on October 2, 2007;
- a non-final Office Action on January 16, 2008;
- a final Office Action on November 26, 2008; and
- an Advisory Action on June 3, 2009.

4. Request for consideration of Information Disclosure Statement (IDS)

Applicants request consideration of the IDS filed December 8, 2008. Applicants note with appreciation the consideration of the IDS filed August 26, 2008.

5. Request for Rejoinder

Claims 29-31 were withdrawn pursuant to an election of species. Because the elected claims are believed to be linked by at least one special technical feature, rejoinder of claims 29-31 is proper, and Applicants respectfully request the same.

6. Provisional Rejection under the Doctrine of Obviousness-Type Double Patenting

Claims 1-6, 8-12, and 32 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-21 and 31 of co-pending Application No. 10/485,456 in view of Willatts, *Lancet* 352: 688 (1998) ("Willatts").

Applicants will file a Terminal Disclaimer to overcome the rejection, if necessary, upon allowance of the claims of either application. Because the rejection is provisional, Applicants reserve the right to traverse the rejection, once the claims of the co-pending applications become allowable.

7. Rejections under 35 U.S.C. § 102(b)

A. Willatts

Claims 1, 13-19 and 32 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Willatts.

Applicants traverse the rejection. Willatts fails to disclose administration of a composition to a subject in an amount that would necessarily achieve a daily arachidonic acid intake of at least 200 mg, as claimed. Nor does Willatts disclose or suggest administering arachidonic acid to a healthy adult person.

For anticipation, a single prior art reference must teach each and every element of the claimed invention, either explicitly or inherently.[1] The Office must establish a reason to believe that an element is in fact an inherent characteristic of the prior art.[2] The Office must further establish that the allegedly inherent characteristic inheres in the prior art teaching beyond probabilities or possibilities.[3]

Willatts discloses administration of a composition (infant formula) to healthy infants. The formula contains a fat supplement with 300-400 mg arachidonic acid per 100 g fat. Willatts, Table 1; p. 689, 1st col., ¶ 1-2. Willatts nowhere provides the daily dosage of arachidonic acid. *See* Willatts, p. 689, 1st col., ¶ 1-2. The Office provides no evidence or reason to believe that Willatts administers this composition in an amount that would necessarily achieve a daily arachidonic acid intake of at least 200 mg, as claimed. In fact, for Willatts to administer 200 mg arachidonic acid daily to infants, Willatts would have to administer ***50-67 g of fat*** to the infant every day to meet the designated amounts. For both of these reasons, the Office has not established *prima facie* anticipation. *See Verdegaal Bros.*, 2 U.S.P.Q.2d at 1053, *Best*, 195 U.S.P.Q. at 433; *Oelrich*, 666 F.2d at 581-82. The rejection thus is improper and should be withdrawn.

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1 *Verdegaal Bros. v. Union Oil Co. Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

2 *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977).

3 *In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981); *see also Ex parte Whalen*, 89 U.S.P.Q.2d 1078, 1083 (Bd. Pat. App. & Int. 2008) (precedential) ("even if some of the [prior art] compositions encompassed by Evans' broad disclosure might have a viscosity of 150 cSt at 40 °C, that possibility is not adequate to support a finding of inherent anticipation.").

B. Kiliaan

Claims 1, 2, 6, 8 and 13-19 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Publication No. 2002/0040058 ("Kiliaan").

Applicants traverse the rejection. Kiliaan fails to disclose administration of a composition to a subject in an amount that would achieve a daily arachidonic acid intake of at least 200 mg, as claimed.

Kiliaan discloses administration of a composition containing eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), dihomo-γ-linolenic acid (DHGLA) and arachidonic acid (AA) as components. Kiliaan, ¶ 38. Kiliaan suggests a daily intake of the EPA, DHA, and DHGLA components but is silent regarding a suggested daily intake of arachidonic acid. Kiliaan, ¶ 38. Kiliaan elsewhere explicitly teaches a daily dose of arachidonic acid of at least 50-100 mg of arachidonic acid. Kiliaan, ¶ 66. The Office provides no evidence or reason to believe that Kiliaan administers this composition in an amount that would necessarily achieve a daily arachidonic acid intake of at least 200 mg, as claimed. For this reason alone, the Office has not established *prima facie* anticipation. *See Verdegaal Bros.*, 2 U.S.P.Q.2d at 1053, *Best*, 195 U.S.P.Q. at 433; *Oelrich*, 666 F.2d at 581-82. The rejection thus is improper and should be withdrawn.

8. Rejections under 35 U.S.C. § 103(a)

A. Willatts in view of Barclay

Claims 1, 2, 6, 8, 9, 13-19, and 32 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Willatts in view of U.S. Patent No. 5,583,019 ("Barclay").

Applicants traverse the rejection. The teachings of Willatts are set forth above. Willatts nowhere provides a daily dosage of arachidonic acid to administer. *See* Willatts, p. 689, 1st col., ¶ 1-2. Barclay suggests supplementing infant formula with arachidonic acid. *See* Barclay, col. 2, lines 47-49. Barclay produces a fungal biomass and oils with certain percentages of arachidonic acid (e.g., Table 8); however, Barclay nowhere teaches or suggests how much arachidonic acid to administer to an infant. Neither reference suggests administering arachidonic acid to a healthy adult person, thus failing to teach at least this limitation of the claims. The combination of

references thus does not teach or suggest administering a composition in an amount sufficient to prevent decline of, improve, or enhance cognitive ability responses of a healthy adult person, where the amount represents a daily arachidonic acid intake of at least 200 mg, as claimed. Because the combined references do not teach or suggest all the elements of the claims, the rejection is improper and should be withdrawn. *See Wilson*, 165 U.S.P.Q. at 496.

The Office argues that Willatts does not discount the notion that higher supplementation of formula with fatty acids would provide an even greater beneficial effect on infant problem solving ability. *See* Office Action, p. 9, ¶ 2. The Office argues that Barclay provides an expectation of success in making formula with a higher percentage of arachidonic acid. *See* Office Action, p. 9, ¶ 3.

Willatts arguably suggests a beneficial effect of infant formula containing some arachidonic acid, among many other components. Willatts, however, nowhere attributes the observed beneficial effect specifically to arachidonic acid. Nor does Willatts suggest that administering more formula generally would have a greater beneficial effect (even if it were possible to deliver more formula to the infants). The Office speculates that the artisan "would expect that higher doses of the active ingredients would have larger effects." An Examiner's speculation, however, cannot substitute for evidence in an obviousness rejection.[4] And, as pointed out above, Willatts would have had to administer ***50-67 g of fat*** every day to achieve a daily arachidonic acid intake of at least 200 mg. Thus, there is no reason to believe that Willatts truly would have suggested a daily arachidonic acid intake of at least 200 mg.

Barclay also arguably suggests a beneficial effect of arachidonic acid in formula, but Barclay nowhere suggests that arachidonic acid would be beneficial in the claimed method of preventing decline of, improving, or enhancing cognitive ability responses of a healthy adult person. *See* Barclay, col. 1, lines 13-36. Nor does Barclay suggest how much arachidonic acid would have a beneficial effect. Thus, Barclay at best would have suggested making the same addition of arachidonic acid to the infant formula of Willatts. As discussed above, however, the infant formula of Willatts likely does not contain enough arachidonic acid to deliver a daily intake of at least 200 mg, as claimed, let alone administering it to an adult.

It is not enough to allege that it was within the skill of the art to increase the amount of arachidonic acid in formula, such that the formula would deliver the claimed daily dosage. The Office must provide some evidence or reason why the artisan would have been motivated to make the proposed modification, and that there be a reasonable expectation of success that it work as planned. *See Whalen*, 89 U.S.P.Q.2d at 1083, 1084. In the absence of such motivation, the rejection is improper. The rejection thus should be withdrawn.

B. Willatts and Barclay further in view of the '891 application

Claims 1-6, 8-19, and 32 stand rejected under §103(a) allegedly as being unpatentable over Willatts and Barclay in view of JP 08-214891 ("the '891 application").

Applicants traverse the rejection. The deficiencies of the combination of Willatts and Barclay are set forth above. The '891 application is directed to manufacturing concentrated fats and oils containing triglycerides with a higher unsaturated fatty acid content. There is no issue on this record whether the artisan knew how to make compositions containing a high concentration of arachidonic acid, in the forms of triglycerides or otherwise. *See* Office Action, p. 11, ¶ 1. But obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success. It must be shown that those of ordinary skill in the art would have had some ***apparent reason*** to modify the known composition in a way that would result in the claimed composition. *See Whalen*, U.S.P.Q.2d at 1084. The '891 application, however, does not provide a reason to modify the combined teachings of McGahon and Willatts to deliver the claimed daily amount of arachidonic acid to a healthy adult person, let alone provide an expectation that this modification would succeed. Nor does the '891 application motivate modifying the combined teachings of Willatts and Barclay to administer arachidonic acid to prevent decline of, improve, or enhance cognitive ability responses of a healthy adult person, as claimed. The combination of references thus does not teach or suggest all the claim elements. The rejection thus is improper and should be withdrawn.

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[4] *See, e.g., KSR Int'l Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1389 (U.S. 2007) (evidence should be explicit); *In re Lee*, 61 U.S.P.Q.2d 1430, 1433-35 (Fed. Cir. 2002) (prohibiting mere speculation).

C. McGahon in view of Willatts

Claims 1, 13-19 and 32 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over McGahon et al., *Neuroscience* 81: 9-16 (1997) ("McGahon") in view of Willatts.

Applicants traverse the rejection. McGahon discloses a correlation between the ability of aged rats to sustain long term potentiation (LTP) in a hippocampus region and decreases in glutamate release and membrane arachidonic acid. *See* McGahon, Abstract. The Office acknowledges that McGahon does not teach treating humans with arachidonic acid supplementation. Office Action mailed July 3, 2008, p. 13. The Office relies on Willatts to suggest applying the method of McGahon to humans. *Id.* at p. 14. The Office alleges that LTP is an indirect measure for cognitive abilities. *See* Office Action mailed March 2, 2009, p. 12.

Applicants do not concede or deny an unproven correlation between an increase in LTP and preventing decline of, improving, or enhancing cognitive ability responses of a healthy adult person.[5] In any event, as noted above, Willatts arguably suggests only a beneficial effect of infant formula containing some arachidonic acid, among many other components. Willatts, however, nowhere attributes the observed beneficial effect specifically to arachidonic acid. Nor does Willatts suggest that administering more formula generally would have a greater beneficial effect (even if it were possible to deliver more formula to the infants).

Even assuming, for the sake of argument only, that LTP and cognitive abilities are correlated, the combined references do not suggest the claimed method. The Office acknowledges that McGahon does not teach treating humans with arachidonic acid supplementation. Willatts suggests, at best, feeding an unspecified amount of arachidonic acid to infants. Taken together, the references do not teach or suggest a daily arachidonic acid intake of at least 200 mg administered to a healthy adult person.

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[5] It is Office's burden to establish the alleged correlation between LTP and cognitive abilities. *See, e.g., KSR Int'l Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1389 (U.S. 2007) (evidence should be explicit); *In re Lee*, 61 U.S.P.Q.2d 1430, 1433-35 (Fed. Cir. 2002) (prohibiting mere speculation as a basis for obviousness).

D. McGahon and Willatts further in view of the '891 application

Claims 1-6, 8-19, and 32 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over McGahon and Willatts as applied to claims 1, 13-19 and 32 above and further in view of the '891 application.

Applicants traverse the rejection. The deficiencies of the combination of McGahon and Willatts are set forth above. The '891 application is directed to manufacturing concentrated fats and oils containing triglycerides with a higher unsaturated fatty acid content. There is no issue on this record whether the artisan knew how to make compositions containing a high concentration of arachidonic acid, in the forms of triglycerides or otherwise. *See* Office Action, p. 11, ¶ 1. But obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success. It must be shown that those of ordinary skill in the art would have had some ***apparent reason*** to modify the known composition in a way that would result in the claimed composition. *See Whalen*, U.S.P.Q.2d at 1084. The '891 application, however, does not motivate modifying the combined teachings of McGahon and Willatts to deliver the claimed daily amount of arachidonic acid to a healthy adult person. Nor does the '891 application motivate modifying the combined teachings of McGahon and Willatts to administer arachidonic acid to prevent decline of, improve, or enhance cognitive ability responses of a healthy adult person, as claimed. The combination of references thus does not teach or suggest all the claim elements. The rejection thus is improper and should be withdrawn.

E. Kiliaan in view of Barclay

Claims 1, 2, and 13-19 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over Kiliaan in view of Barclay. Applicants traverse the rejection.

Applicants traverse the rejection. Kiliaan fails to disclose administration of a composition to a subject in an amount that would achieve a daily arachidonic acid intake of at least 200 mg, as claimed. Barclay administers arachidonic acid to infants, not healthy adult persons, as claimed. Nor does Barclay teach how much arachidonic acid to administer even to an infant. The combination of references thus does not teach or suggest administering a composition in an amount sufficient to prevent decline of, improve, or enhance cognitive ability

responses of a healthy adult person, where the amount represents a daily arachidonic acid intake of at least 200 mg, as claimed. The rejection thus is improper and should be withdrawn.

F. Kiliaan in view of the '891 application

Claims 1-6, and 8-19 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over Kiliaan in view of the '891 application.

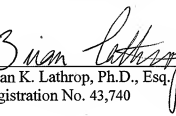
Applicants traverse the rejection. Kiliaan fails to disclose administration of a composition to a subject in an amount that would achieve a daily arachidonic acid intake of at least 200 mg, as claimed. The '891 application is directed to manufacturing concentrated fats and oils containing triglycerides with a higher unsaturated fatty acid content. There is no issue on this record whether the artisan knew how to make compositions containing a high concentration of arachidonic acid, in the forms of triglycerides or otherwise. *See* Office Action, p. 11, ¶ 1. But obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success. It must be shown that those of ordinary skill in the art would have had some ***apparent reason*** to modify the known composition in a way that would result in the claimed composition. *See Whalen*, U.S.P.Q.2d at 1084. The '891 application, however, does not motivate modifying Kiliaan to deliver the claimed daily amount of arachidonic acid to a healthy adult person. Nor does the '891 application motivate modifying Kiliaan to administer arachidonic acid to prevent decline of, improve, or enhance cognitive ability responses of a healthy adult person, as claimed. The combination of references thus does not teach or suggest all the claim elements. The rejection thus is improper and should be withdrawn.

CONCLUSION

If there are any other fees due in connection with this filing, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
DRINKER, BIDDLE & REATH LLP

Date: February 26, 2010

By: 
Brian K. Lathrop, Ph.D., Esq.
Registration No. 43,740

1500 K Street, N.W., Suite 1100
Washington, D.C. 20005-1209
T: 202-842-8862
F: 202-842-8465